K112913

DEC 16 2011

510(K) SUMMARY

A. Submitter Information

DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact Person: Laura Bleyendaal
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Raynham, MA 02767
Telephone number: (508) 828-3267
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B. Date Prepared December 8, 2011

C. Device Name

Trade/Proprietary Name: SPOTLIGHT™ Access System

Common/Usual Name: Self-retaining retractor for neurosurgery

Classification Name: Retractor, Self-Retaining, For Neurosurgery per 21 CFR § 882.4800

D. Predicate Device Name

Trade name: DePuy Spine, Inc. SPOTLIGHT™ Access System (K062814)
Bright Medical Dilation Retractor System (K992898)

E. Device Description

The SPOTLIGHT™ Access System consists of a series of dilators and tubular retractors with and without integrated light source of various lengths and diameters designed to provide minimally invasive surgical access to the spine.
The SPOTLIGHT™ Access System also contains Class I manual surgical instruments and cases that are considered exempt from premarket notification.

F. Intended Use

The SPOTLIGHT™ Access System is intended to provide the surgeon with minimally invasive surgical access to the spine by ensuring the placement/positioning of the port, down to the posterior and posterolateral bony spinal elements. These ports provide access to the spinal site which can be visualized using a microscope or loupes, and through which surgical instruments can be manipulated.

F. Summary of Similarities and Differences in Technological Characteristics

i. The wall thickness of the proposed ports varies from the proximal to the distal end. The wall thickness of the proposed ports is less than that of the previously cleared SPOTLIGHT™ Access System ports and greater than that of the previously cleared Bright Medical Dilation Retractor System ports.

ii. The proposed ports have a permanently fixed handle at the proximal end for manual manipulation.

iii. Like the previously cleared Bright Medical Dilation Retractor System ports, the proposed ports do not contain an integrated light source.

iv. The proposed port lengths and outer diameters are consistent with previously cleared SPOTLIGHT™ Access System port offerings.

v. The proposed ports are manufactured from a different material (anodized 6061 T6 aluminum) than the previously cleared SPOTLIGHT™ Access System ports and Bright Medical Dilation Retractor System ports.

G. Materials

The subject ports are manufactured from anodized 6061 T6 aluminum. The material conforms to the following ASTM standards: B211 and B221.

H. Performance Data

Test System	Study Results	Conclusion
Compressive Force Testing	Met the same specification as the predicate device	Pass
Static Torque Testing on Fixed Handle Connection	All samples met the acceptance criteria	Pass
Validation of Reprocessing Instructions	An evaluation of the devices for equivalency to previously validated devices for reprocessing cleaning and sterilization was performed and documented according to DePuy Spine, Inc. internal procedures.	Pass
USP Physiochemical Test for Plastics	Non-volatile Residue- Conforms Residue on Ignition- Conforms Heavy Metals- Conforms Buffering Capacity- Conforms	Conforms- passes all acceptance criteria
In vitro Cytotoxicity Agar Diffusion	Cell culture treated with test sample exhibited Slight (Grade 1) Reactivity	Non-cytotoxic
In vitro Cytotoxicity MEM Elution Test	Cell culture treated with sample extract exhibited no cells lysis (Grade 0 Reactivity)	Non-cytotoxic
Sensitization Test - Guinea Pig Maximization	No significant difference in biological response between test article and negative control.	Non- sensitizing
Irritation/Intracutaneous Reactivity USP Intracutaneous Test	The difference between the mean scores for the sample extracts and corresponding blanks was 0.5 or less.	Non-irritating
Acute Systemic Toxicity USP Systemic Injection Test	None of the animals treated with the sample extracts showed any signs of toxicity and all gained weight.	Non-toxic
In vitro Genotoxicity - Ames Bacterial Mutagenicity Assay	None of the five tester strains produced two-fold increases in the number of revertants. The spot tests showed no zone of increased reversion or of inhibition.	Non-mutagenic

Implantation USP Implantation Test	No encapsulation was observed grossly in any of the test or control sites, and no irritation was observed microscopically at the test sites compared to the control sites.	The test material met the requirements of the USP Implantation Test when implanted for seven days
In vitro Hemolysis Extraction Method	Less than 5% hemolysis- A test sample with 5% or less hemolysis is considered non-hemolytic.	Non-hemolytic
In vitro Hemolysis Direct Contact	Less than 5% hemolysis- A test sample with 5% or less hemolysis is considered non-hemolytic.	Non-hemolytic
Material-Mediated Pyrogenicity USP Rabbit Pyrogen Test	No rabbit showed an individual rise in temperature of 0.5°C or more.	Non-pyrogenic

I. Conclusion

Both the performance testing and substantial equivalence justification demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 16 2011

Johnson & Johnson
c/o Ms. Laura Bleyendaal
Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K112913
Trade/Device Name: SPOTLIGHT™ Access System
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-retaining retractor for neurosurgery
Regulatory Class: Class II
Product Code: GZT
Dated: December 1, 2011
Received: December 2, 2011

Dear Ms. Bleyendaal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K112913

Device Name: SPOTLIGHT™ Access System

Indications For Use:

The SPOTLIGHT™ Access System is intended to provide the surgeon with minimally invasive surgical access to the spine by ensuring the placement/positioning of the port, down to the posterior and posterolateral bony spinal elements. These ports provide access to the spinal site which can be visualized using a microscope or loupes, and through which surgical instruments can be manipulated.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ___

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JEFFREY TOY

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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